In particular, the Examiner contends that claims 32, 40 and 43 lack sufficient antecedent basis for the limitation "containing the nucleic acid" of a preceding claim. In response, the claims have been amended as suggested by the Examiner. Support for the amendment can be found in the specification at page 27, line 28 to page 28, line 1. Applicant submits that this amendment merely clarify the subject matters claimed and do not alter the scope of the claims. The rejection is thus obviated.

The Examiner also contends that claim 48 lacks antecedent basis for the limitation that the isolated nucleic acid is a RNA. Applicant respectfully disagree. The recitations of claims 33-35 and 38 do not limit the claimed nucleic acid to a complementary DNA (cDNA). Rather, the claimed isolated nucleic acid need only comprise the nucleotide sequence of a cDNA. Thus, a RNA molecule that comprises the same nucleotide sequence as the cDNA is encompassed by claims 33-35 and 38, and which is specifically claimed in claim 48. Accordingly, the rejection is in error and should be withdrawn.

3. The Rejections Under 35 U.S.C. § 112, First Paragraph Are Obviated

Claims 34, 36-43, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, for lack of written description. The Examiner alleges that the rejection is based on inclusion of new matter in the claims.

Specifically, the Examiner points out that Figure 2 shows that the FbN-3 domain of SEQ ID NO: 2 begins at amino acid residue 1087. In response, claim 34 has been amended to recite the amino acid residue 1087 of SEQ ID NO: 2. Claim 38 has also been amended to recite that the polypeptide comprises, inter alia, the amino acid sequences of 984-1086 and 1087-1185. Support for the amendment can be found in Figure 2. Accordingly, the rejection of claim 34, claim 38 and dependent claims is obviated.

With respect to claim 41, the Examiner points out that there does not appear to be adequate support for "nucleotides 453-5169 of SEQ ID NO: 1". In response, claim 41 has been amended to recite "nucleotide 453-5168 of SEQ ID NO: 10" which is fully supported in the specification at page 13, line 8. Accordingly, the rejection of claim 41 and dependent claims is obviated.

Claims 33- 44 and 46-49 are rejected under 35 U.S.C. 112, first paragraph, for lack of written description. The Examiner alleges that possible variations of the structure of the polypeptides encoded by the claimed nucleic acids is extensive, and that hybridization can occur between short stretches of sequence identities. The Examiner also

points out that unidentified sequences may be present and may in fact be the dominant contributor of the structure of the polypeptides encoded by the claimed nucleic acids. The Examiner contends that there is a lack of identifying characteristics or testable functions shared among members of the claimed genus. Applicant respectfully traverses.

In order to provide an adequate written description, the specification must reasonably convey to the artisan that the inventor had possession at that time of the claimed subject matter. While a patent applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the applicant invented what is claimed. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991) (citing In re Gosteli, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989)).

First, contrary to the Examiner's allegation that members of the claimed genus lack shared identifying characteristics and testable function, Applicant respectfully submits that the claimed nucleic acids either hybridizes under defined conditions to nucleic acids consisting of a recited sequence, or encodes a portion of the disclosed DS-CAM protein. The chemical structure of the claimed genus of nucleic acid molecules are described and well known in the art (e.g., DNA, RNA) and that the variation of nucleotide sequence within the claimed genus is also well defined by the functional characteristics of specifically binding under defined hybridizing conditions to nucleic acid molecules of known sequences.

The Guidelines to the Examination of Patent Applications Under 35 U.S.C. § 112, first paragraph for written description provides:

> "To satisfy the written description requirement, a patent specification must describe the claimed invention . . . . using . . . structures, figures, diagrams and formulas that fully set forth the claimed invention. Possession may be shown . . . including . . . actual reduction to practice . . . or by disclosure of drawings or structural chemical formulas . . . or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention."

(F.R. 66(4) p.1104). See also footnote 42 of the Guidelines (F.R. 66(4) p.1110) wherein it is stated that examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length, and also detailed restriction enzyme maps, antibody cross-reactivity, unique cleavage by particular enzymes. One of skill in the art would recognize from the combination of identifying structural and functional characteristics disclosed in the specification that Applicant has possession of the

claimed genus of nucleic acid molecules. In fact, the skilled person can readily recognize and determine whether a nucleic acid molecule falls within the pending claims by either comparing the sequence of the molecule with the sequences provided in the application (e.g., claims 38 and 44) and/or performing a hybridization reaction under defined conditions with the nucleic acid molecule(s) described in the present application (e.g., claims 33-35). There is sufficient distinguishing identifying characteristics in the specification to show that Applicant was in possession of the claimed nucleic acid molecules. Moreover, Applicant submits that possession of the claimed nucleic acid molecules have been shown by actual reduction to practice. See for example, the cDNA probe "E51" (SEQ ID NO: 3) which was used to identify the various DS-CAM clones by hybridization (see Example 3, in particular page 53, line 9). As such, Applicant submits that adequate written description has been provided.

In response to the Examiner's comment that the claims encompass variants which encode proteins that may lack testable functional activities of DS-CAM protein, Applicant respectfully points out that description of a testable biological function of a protein encoded by the claimed nucleic acid molecule and correlation of such biological function to the structure of the claimed nucleic acid molecule is not an absolute requirement for an adequate written description under 35 U.S.C. §112, first paragraph. As discussed above, the structure of the claimed nucleic acid molecules (i.e., their sequences) can be correlated to their functional ability to hybridize to sequences disclosed in the specification. This relevant identifying characteristics is shared by all members of the genus of claimed molecules. In addition, even though the biological function of the protein products encoded by the claimed nucleic acid molecules may not be fully characterized, Applicant points out that one skilled in the art would readily recognize that a representative number of such protein products can readily be distinguished by their abilities to bind specifically or cross-react with antibodies that are raised against DS-CAM proteins or fragments thereof. In sum, the description in the present application clearly allows persons of ordinary skill in the art to recognize that the applicant invented what is claimed.

Specifically, claims 33-35 describes a genus of polynucleotides by a property (i.e., hybridizable under defined conditions to known sequences) that readily distinguishes the claimed polynucleotides from other materials. To expedite prosecution and clarify the scope, the claims have been amended to particularly point out that the claimed nucleic acid molecules hybridize with the sequences disclosed in the specification over substantially the

entire length of the disclosed sequences. Thus, one of skill in the art can readily isolate the claimed polynucleotides of claims 33-35 and distinguish it from other polynucleotides by performing a hybridization under conditions as recited in the claims.

Regarding claim 38, Applicant respectfully points out that given the genetic code, one of ordinary skill in the art can recite every nucleotide sequence that encodes the segments of amino acid sequences of SEQ ID NO: 2 as disclosed in the specification.

Regarding claim 41, Applicant respectfully points out that each of the claimed nucleic acid molecules comprises either *the entire* nucleotide sequence as set forth in any of one of the listed nucleotide sequences or a specific subsequence of a disclosed nucleotide sequence as recited. Contrary to the Examiner's contention, claim 41 is not drawn to nucleic acid molecules comprising *any* subsequences of the listed nucleotide sequences. Claim 41 has been amended to merely clarify the subject matters claimed and the amendment does not alter the scope of the claim.

Claims 44 recite oligonucleotides corresponding to one of SEQ ID NOS: 11, 7 or 8. The oligonucleotides are described by structural information sufficient to distinguish the claimed oligonucleotides from other nucleic acid molecules. For example, given the amino acid sequence of SEQ ID NO: 11 and the genetic code, the skill person can readily recite the nucleotide sequences that encode the polypeptide, and subsequences thereof that is at least 15 nucleotides in length. As discussed in the specification, *inter alia*, on page 58, lines 9-14, SEQ ID NOs: 5 and 6 are nucleotide sequences that hybridized to DS-CAM nucleic acid molecules and facilitated their amplification by polymerase chain reaction. One of skill in the art would readily recognize that nucleic acid molecules comprising any one of these SEQ IDs would hybridize under the stated stringency conditions to the defined nucleotide sequences as recited in the claims. Thus, the specification also provides representative examples of nucleic acid molecules that are encompassed by the genus of oligonucleotides of Claim 44.

Claim 33-44 and 46-49 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner contends that the specification does not provide enablement of variants of SEQ ID NO: 1 or 10, subfragments thereof, nucleic acids that encode fragments of polypeptides of SEQ ID NO: 2 or 11, and various oligonucleotides. The Examiner referred to the alleged lack of written description of the invention and concluded that the skilled artisan would not know how to make the claimed nucleic acids.

The Examiner also alleged that the function of polypeptides encoded by the nucleic acids that hybridize is unpredictable, and hence nucleic acids that encode such polypeptides lack a testable function. The Examiner indicated that undue experimentation is required to determine which subsequences would have the function of the full length polypeptide and to identify the corresponding nucleic acid subsequences. Referring to claim 44, the Examiner also indicated that undue experimentation is required to select a particular oligonucleotide sequence from a SEQ ID NO:. Applicant respectfully traverses.

According to applicable case law, under 35 U.S.C. § 112, where a disclosure provides considerable direction and guidance on how to practice the invention and presents working examples, and where, at the time of application, the skill in the art was quite high and the methods needed to practice the invention well known, a conclusion of enablement should be made. In re Wands, 858 F.2d 731, 740, 8 U.S.P.Q.2d. 1400, 1406 (Fed. Cir. 1988). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). An invention is enabled even though the disclosure may require some routine experimentation to practice the invention. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

First, Applicant respectfully points out that the skill in the relevant art (i.e., making and using nucleic acid molecules) is extremely high, and working examples are provided in the specification (e.g, use of clone E51 to identify DS-CAM clones and use of oligonucleotides to amplify DS-CAM sequences).

Applicant submits that where the amino acid or nucleotide sequences are provided, or where nucleic acid probes and hybridization conditions are provided, no undue experimentation is needed to synthesize or clone the desired nucleic acid molecules. In this instance, Applicant submits that the specification has provided both the relevant nucleotide or amino acid sequences for chemical synthesis of the claimed nucleic acid molecules, and the nucleotide or amino acid sequences for the probe and applicable hybridization conditions for cloning the claimed nucleic acid molecules. Accordingly, no undue experimentation is required to make the claimed nucleic acid molecules.

With respect to the use of the claimed nucleic acid molecules, Applicant submits that one of the non-limiting use is in hybridization assays for detection and identification of DS-CAM and related sequences in biological and clinical samples. The

use of nucleic acid molecules as probes in such assays are very well known in the art, and need not be taught in the specification. Other possible uses of the claimed nucleic acid molecules include the expression of the polypeptide encoded by the nucleic acid molecules. The specification teaches how to use such nucleic acid molecules to recombinantly produce polypeptides in host cells (see pages 27-31). An enabling description for a process or method requires sufficient disclosure as to "how to carry out the claimed process." In re Barrett, 440 F.2d 1391, 1392 (C.C.P.A. 1971). A patent need not teach, and preferably omits, what is well known in the art. Hybritech Inc. v. Monoclonal Antobodies, Inc. 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), cert. Denied; 480 U.S. 947 (1987). Applicant respectfully points out that the allegation that the biological function of a polypeptide that can be encoded by a claimed nucleic acid molecule is unpredictable bears no relevance to whether the use of that nucleic acid molecule in expression or in hybridization assays requires experimentation.

Applicant submits that given the skill of those in the art, the presence of working examples, and the predictability associated with the uses of the claimed nucleic acid molecules (e.g., in hybridization assays or in recombinant expression), the experimentation necessary is not undue, and if required is merely routine. As such, the rejection is erroneous and should be withdrawn.

In view of the foregoing, Applicant submits that the rejections under 35 U.S.C. § 112, first paragraph, should be withdrawn.

4. The Rejections Under 35 U.S.C. § 102 Are Obviated

Claims 33, 34, 36, 37, 41-44, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Genexpress cDNA Program (GenBank, Accession #F13426). The Genbank sequence accession #F13426 discloses a 309 bp fragment of nucleic acid which overlaps with SEQ ID NO: 1 starting from nucleotides 5280 to 5589 which encodes 1610 to 1712 of the amino acid sequence of SEQ ID NO: 2. F13426 also overlaps with SEQ ID NO: 10 starting from nucleotides 5133 to 5398, part of which encodes the terminal portion of the amino acid sequence of SEQ ID NO: 11 from 1561 to 1571.

In response, Applicant has amended claim 33 to recite that the second nucleic acid consists of a nucleotide sequence that encodes residue 1 to 1473 of the amino acid sequence of SEQ ID NO: 11. Applicant submits that the claim amendment is supported by Figure 3 and the sequence listing. The recited amino acid sequence of SEQ ID

NO:11 from residue 1 to 1473 represents all the amino acid residues encoded by exon sequences upstream of the exon that consists of the 5' end of the alternative splice site as illustrated in Figure 3. The alternative splice site occurs at nucleotides 5132 of SEQ ID NO. 1 and 10, resulting in the removal of nucleotides 5133-5323 of SEQ ID NO. 1. As shown in Figure 3, the exon that consists of the alternative splice site and that has 294 bp starts with nucleotide 4873 which encodes amino acid residue 1474 of SEQ ID NO: 2 and 11. As a result of the amendment, there is no overlap in sequence between F13426 and the second nucleic acid molecule to which the claimed nucleic acid of claim 33 hybridizes. Applicant submits that the rejection of claim 33 and dependent claims is obviated and should thus be withdrawn.

With respect to claim 34, Applicant reiterates that there is no overlap between F13426 and either of the nucleotide sequences encoding the two recited regions of SEQ ID NO: 2, namely residues 24 to 126, and residues 1087 to 1185. Claim 34 has been amended to clarify that the claimed nucleic acid hybridizes to fragments of SEQ ID NO: 1 that encodes amino acids 24 to 126, and amino acid 1087 to 1185. The recited fragments of SEQ ID NO:1 do not overlap with F13426. Applicant submits that the rejection of claim 34 and dependent claims is obviated.

Claim 41 has been amended to recite "the nucleotide sequence" and thus avoid the interpretation that any subsequence of the disclosed sequences are encompassed by claim 41. Accordingly, the rejection of claim 41 is obviated.

Claim 44 has been amended to recite that the claimed oligonucleotide encodes only amino acids 1 to 1473 of SEQ ID NO: 2 or a subsequence thereof that is at least 15 nucleotides long. Accordingly, the rejection of claim 44 and dependent claims 45 and 46 is obviated.

In view of the foregoing, the rejections of claims 33-38, 41, 47 and 48 should be withdrawn.

Conclusion

Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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32 (amended). An isolated cell containing the nucleic acid of claim 1 or the vector of claim 31.

33 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA which hybridizes under high stringency conditions to substantially the entire complement of a second nucleic acid encoding [the] amino [acid sequence set forth in] acids 1 to 1473 of SEQ ID NO:11, wherein said high stringency conditions comprise hybridizing in 5X Denhardt's solution, 5X SSPE and 0.2% sodium dodecylsulfate at 42°C, followed by washing in 0.1X SSPE and 0.1% Sodium dodecylsulfate at 65°C.

34 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA that hybridizes under high stringency conditions to substantially the entire complement of a second nucleic acid consisting of the nucleotide sequence [set forth in] of a fragment of SEQ ID NO:1 that encodes amino acids 24 to 126 of SEQ ID NO:2 and that hybridizes under high stringency conditions to substantially the entire complement of a third nucleic acid consisting of the nucleotide sequence of a fragment of [set forth in] SEQ ID NO:1 that encodes amino acids [1069] 1087 to 1185 of SEQ ID NO:2, wherein said high stringency conditions comprise hybridizing in 5X Denhardt's solution, 5X SSPE and 0.2% sodium dodecylsulfate at 42°C, followed by washing in 0.1X SSPE and 0.1% Sodium dodecylsulfate at 65°C.

35 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA which hybridizes under high stringency conditions to substantially the entire complement of a second nucleic acid consisting of the nucleotide sequence set forth in SEQ ID NO:7 or SEQ ID NO:8, wherein said high stringency conditions comprise hybridizing in 5X Denhardt's solution, 5X SSPE and 0.2% sodium dodecylsulfate at 42°C, followed by washing in 0.1X SSPE and 0.1% Sodium dodecylsulfate at 65°C.

38 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA which encodes a polypeptide comprising at least one of the amino acid sequences selected from the group consisting of: amino acids 1-23, 24-126, 127-225, 226-316, 317-409, 410-506, 507-603, 604-697, 698-792, 793-887, 888-983, 984-[1067] 1086, [1068] 1087-1185, 1186-1281, 1282-1375, 1376-1471, 1472-1594, 1595-1616, and 1617-1910 of SEQ ID NO:2.

40 (amended). An isolated cell containing the nucleic acid of claim 38 or the vector of claim 39.

41 (amended). An isolated nucleic acid molecule comprising [a] the nucleotide sequence set forth in SEQ ID NO:1, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, nucleotides 453-6185 of SEQ ID NO:1 or nucleotides 453-5168 of SEQ ID NO:[1] 10.

43 (amended). An isolated cell containing the nucleic acid of claim 41 or the vector of claim 42.

44(amended). An oligonucleotide comprising at least 15 nucleotides of (a) a nucleotide sequence that encodes [the polypeptide] amino acids 1 to 1473 of SEQ ID NO:11; (b) the nucleotide sequence set forth in SEQ ID NO. 7 or 8; or (c) the complement of the nucleotide sequence of (a) or (b).

EXHIBIT B

THE CLAIMS WHICH WILL BE PENDING UPON ENTRY OF THE PRESENT AMENDMENT U.S. PATENT APPLICATION SERIAL NO. 09/956,991

1 (amended). An isolated nucleic acid consisting essentially of (a) a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 or 11; and (b) the complement of the nucleotide sequence of (a).

31. A vector comprising the isolated nucleic acid of claim 1.

32 (amended). An isolated cell containing the nucleic acid of claim 1 or the vector of claim 31.

33 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA which hybridizes under high stringency conditions to substantially the entire complement of a second nucleic acid encoding amino acids 1 to 1473 of SEQ ID NO:11, wherein said high stringency conditions comprise hybridizing in 5X Denhardt's solution, 5X SSPE and 0.2% sodium dodecylsulfate at 42°C, followed by washing in 0.1X SSPE and 0.1% Sodium dodecylsulfate at 65°C.

34 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA that hybridizes under high stringency conditions to substantially the entire complement of a second nucleic acid consisting of the nucleotide sequence of a fragment of SEQ ID NO:1 that encodes amino acids 24 to 126 of SEQ ID NO:2 and that hybridizes under high stringency conditions to substantially the entire complement of a third nucleic acid consisting of the nucleotide sequence of a fragment of SEQ ID NO:1 that encodes amino acids 1087 to 1185 of SEQ ID NO:2, wherein said high stringency conditions comprise hybridizing in 5X Denhardt's solution, 5X SSPE and 0.2% sodium dodecylsulfate at 42°C, followed by washing in 0.1X SSPE and 0.1% Sodium dodecylsulfate at 65°C.

35 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA which hybridizes under high stringency conditions to

substantially the entire complement of a second nucleic acid consisting of the nucleotide sequence set forth in SEQ ID NO:7 or SEQ ID NO:8, wherein said high stringency conditions comprise hybridizing in 5X Denhardt's solution, 5X SSPE and 0.2% sodium dodecylsulfate at 42°C, followed by washing in 0.1X SSPE and 0.1% Sodium dodecylsulfate at 65°C.

36. A vector comprising the isolated nucleic acid of claim 33, 34, or 35.

37. An isolated cell containing the nucleic acid of claim 33, 34, or 35.

38 (twice amended). An isolated nucleic acid comprising the nucleotide sequence of a complementary DNA which encodes a polypeptide comprising at least one of the amino acid sequences selected from the group consisting of: amino acids 1-23, 24-126, 127-225, 226-316, 317-409, 410-506, 507-603, 604-697, 698-792, 793-887, 888-983, 984-1086, 1087-1185, 1186-1281, 1282-1375, 1376-1471, 1472-1594, 1595-1616, and 1617-1910 of SEQ ID NO:2.

39. A vector comprising the isolated nucleic acid of claim 38.

40 (amended). An isolated cell containing the nucleic acid of claim 38 or the vector of claim 39.

41 (amended). An isolated nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO:1, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, nucleotides 453-6185 of SEQ ID NO:1 or nucleotides 453-5168 of SEQ ID NO:10.

42. A vector comprising the isolated nucleic acid of claim 41.

43 (amended). An isolated cell containing the nucleic acid of claim 41 or the vector of claim 42.

44(amended). An oligonucleotide comprising at least 15 nucleotides of (a) a nucleotide sequence that encodes amino acids 1 to 1473 of SEQ ID NO:11; (b) the

nucleotide sequence set forth in SEQ ID NO. 7 or 8; or (c) the complement of the nucleotide sequence of (a) or (b).

45. The oligonucleotide of claim 44 wherein the oligonucleotide sequence consists essentially of SEQ ID NO:5 or SEQ ID NO:6.

46. A kit for detecting the presence of a nucleic acid in a sample comprising in a package at least one oligonucleotide of claims 44 or 45.

47. The isolated nucleic acid of claim 1, 33, 34, 35, 38 or 41 which is cDNA.

48. The isolated nucleic acid of claim 1, 33, 34, 35, 38 or 41 which is RNA.

49. A method for making of a Down Syndrome-Cell Adhesion Molecule polypeptide or fragment thereof, said method comprising the steps of culturing the cell of claim 32, 37, 40 or 43 under conditions suitable for expression of said Down Syndrome-Cell Adhesion Molecule protein, and isolating the expressed Down Syndrome-Cell Adhesion Molecule protein.

EXHIBIT C

Marked up version of a paragraph in the specification

[Figure 2 shows]Figures 2A-2B show the predicted amino acid sequence of the human DS-CAM1 protein corresponding to SEQ ID NO: 2 and a schematic structure. **IG**: Immunoglobulin type C2-domain. **FbN**: Fibronmection type III domain. The bold **C**s in the amino acid sequence indicates Cysteine residues forming disulfide bonds in the Ig-like type-C2 domains. The bold **NXS** and **NXT** in the amino acid sequence correspond to potential N-glycosylation sites.

EXHIBIT D

Marked up version of the Abstract of U.S. Patent Application Serial No. 09/956,991

In accordance with the present invention, there are provided [novel] Down Syndrome-Cell Adhesion Molecule (DS-CAM) proteins. Nucleic acid sequences encoding such proteins and assays employing same are also disclosed. The invention DS-CAM proteins can be employed in a variety of ways, for example, for the production of anti-DS-CAM antibodies thereto, in therapeutic compositions and methods employing such proteins and/or antibodies. DS-CAM proteins are also useful in bioassays to identify agonists and antagonists thereto.